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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,802	02/12/2004	Sheng-Ping (Samuel) Zhong	03-235	5369

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

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04/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,802	ZHONG, SHENG-PING (SAMUEL)	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,10-17 and 19-28* is/are pending in the application.

4a) Of the above claim(s) *10-16,20,24 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,17,19,21-23,25,27, and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicant's: (a) response, filed on 1 December 2009; and (b) amendment and response, filed on 24 July 2009.
- The claim objections presented in the previous Office action are withdrawn in view of the claim amendments filed on 24 July 2009.

* * * * *

Claim Objections

Claim 10 is objected to because of the following informality: The status identifier of claim 10 indicates that it is "Withdrawn". However, this claim depends from claim 6, which has been cancelled. Since claim 10 is currently pending, it must depend from a currently pending claim. Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 17, 19, 21-23, 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/026532 ("Weber").

Weber teaches a medical article comprising a release region (*see* page 2, lines 22-28), further comprising:

- the implantable or insertable medical device of instant claim 1 (*see* page 20, lines 16-21);
- the polymeric carrier comprising a first polymer of instant claim 1 (*see* page 8, lines 5-15);
- the drug loaded nanoparticles dispersed within the polymeric carrier of instant claim 1 (*see* page 5, line 18; page 10, line 27; page 11, lines 14-16);
- the layered silicate material (phyllosilicate) of instant claim 1 (*see* page 9, line 4);
- the hydrophilic therapeutic agent of instant claim 1 (*see* page 11, line 17 – page 12, line 6; *e.g.* acetylsalicylic acid);
- the hydrophobic polymer of instant claim 1 (*see* page 8, lines 5-15; *e.g.* polyolefin block copolymer);
- the hydrophilic second polymer of claim 1 (*see* page 8, lines 5-15; *e.g.* polyacrylics); it is noted that Weber teaches that the matrix material can be a polymer blend (*see* page 8, line 4) – as such, Weber envisions using a combination of any of the matrix materials listed in the subsequent paragraph (*see* page 8, lines 5-15) which includes a hydrophobic polymer such as a polyolefin block copolymer and a hydrophilic polymer such as a polyacrylic polymer);
- the disposal over at least a portion of the medical article substrate of instant claim 17 (*see* page 10, lines 24-26; figure 1);

- the coronary or peripheral vasculature implantable or insertable medical device of instant claim 19 (*see* page 20, lines 16-21);
- the catheter of instant claim 21 (*see* page 20, line 19);
- the antithrombotic agent of instant claim 22 (*see* page 11, line 18);
- the smectite silicate material of instant claim 23 (*see* page 9, line 4);
- the method of instant claim 25 (*see* page 6, lines 3-15);
- the overlapping cross-sectional length of instant claim 27 (*see* page 8, line 20); and
- the olefin polymer of instant claim 28 (*see* page 8, lines 5-15).

Weber does not provide an explicit example or embodiment of an implantable or insertable medical device comprising a release region, in turn comprising a polymeric carrier comprising a first polymer and drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising a layered silicate material and a first therapeutic agent. However, based on the teachings cited above, Weber explicitly teaches each of the structural features being claimed in the same configuration being claimed, i.e. nanoparticles comprising a therapeutic agent dispersed in a polymer which in turn is coated onto an implantable or insertable medical devise. As such, Weber reads on the instant application, as claimed.

Weber explains that the disclosed device is beneficial because it provides targeted and controlled delivery of therapeutic agents to a desired treatment site (*see* page 11, lines 5-6).

Weber does not explicitly disclose the placement of the therapeutic agent in the spaces between adjacent layers of the silicate material of each silicate particle to form a depot. However, Weber teaches nanoparticles made of the same material being instantly claimed, *i.e.*, smectite silicate (*see* page 9, line 4), and a hydrophilic therapeutic agent (*see* page 11, line 17 – page 12, line 6; *e.g.* acetylsalicylic acid) associated with said nanoparticles (*see*, *e.g.*, page 11, lines 14-15). The placement of a hydrophilic therapeutic agent in the spaces between the adjacent layers of the silicate material is a property of interaction between the silicate and the therapeutic agent. Properties are the same when the structure and composition are the same. *In re Fitzgerald*, 205 USPQ 594.

Weber does not disclose the spacing between adjacent layers within the silicate particles recited in instant claim 27. However, Weber teaches use of the same silicate as the instant application, *i.e.*, smectite silicate (*see* page 9, line 4), and spacing between adjacent layers is an inherent feature of the silicate.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose an implantable or insertable medical device comprising a polymeric carrier comprising a first polymer and drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising a layered silicate material and a first therapeutic agent, as taught by Weber. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides targeted and controlled delivery of therapeutic agents to a desired treatment site, as explained by Weber (*see* above).

*

2. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/026532 ("Weber") in view of U.S. Patent No. 6,743,463 ("Weber II").

Weber teaches a medical article comprising a release region (*see* above). The disclosed article comprises the polyolefin-polyvinylaromatic block copolymer of instant claim 3 (*see* page 8, lines 5-15).

Weber explains that the disclosed device is beneficial because it provides targeted and controlled delivery of therapeutic agents to a desired treatment site (*see* page 11, lines 5-6).

Weber differs from the instant application in that it does not teach halofuginone as a therapeutic agent.

Weber II teaches an insertable medical device, such as a stent (*see* col. 2, line 27). The device may be coated with a nanocomposite material comprising nanoparticles of clay (*see* col. 10, line 19) and with a biologically active material (*see* col. 10, lines 51-52) such as halofuginone (*see* col. 12, line 7). Weber II teaches that nanoparticles of bioloigically active materials and non-active materials are useful for the disclosed coating formulation (*see* col. 13, lines 3-4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a vascular medical device comprising a release region, further comprising a polymeric carrier and nanoparticles comprising halofuginone, as taught by Weber in view of Weber II. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it

provides targeted and controlled delivery of therapeutic agents to a desired treatment site, as explained by Weber (*see* above).

* * * * *

Response to Arguments

Applicant's arguments filed on 24 July 2009 have been fully considered but they are not persuasive.

Applicant argues that Weber and Weber II are moot in view of the amendment to claim 1. Examiner respectfully disagrees. As explained in the substantive rejection above, Weber teaches that the matrix material can be a polymer blend (*see* page 8, line 4). As such, Weber envisions using a combination of any of the matrix materials listed in the subsequent paragraph (*see* page 8, lines 5-15) which includes a hydrophobic polymer such as a polyolefin block copolymer and a hydrophilic polymer such as a polyacrylic polymer.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615